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Comparison of three high flow oxygen therapy delivery devices

Submission date	Recruitment status	[_] Prospectively registered
17/08/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/09/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/10/2016	Respiratory	

Plain English summary of protocol

Background and study aims
The goal of oxygen therapy is to treat or prevent hypoxemia (low concentration of oxygen in the blood). Many different devices can be used to achieve this goal in spontaneously breathing patients. In intensive care unit (ICU) patients, high flow devices provide oxygen at flow rates high enough to completely satisfy the patient's needs. High flow oxygen therapy is provided by various techniques. The aim of this study is to compare three commonly used oxygen therapy devices (Optiflow™, Boussignac™, and standard facemask with a reservoir bag) to see whether they provide different levels of oxygen, airway pressure, and breathing comfort for the same oxygen flow.

Who can participate?
Patients aged 18 and over who are in the intensive care unit being treated with a tracheostomy tube to help them breathe

What does the study involve?
After their tracheostomy tube is removed participants are treated with the three oxygen therapy devices (Optiflow™, Boussignac™, and standard facemask with a reservoir bag) in a random order. Airway pressure and amount of oxygen inhaled are measured using a catheter (tube) inserted through the hole left by the tracheotomy tube. Comfort is also evaluated.

What are the possible benefits and risks of participating?
The results of this study could help determine which oxygen therapy is the most effective for a given patient. There are no risks involved in this study.

Where is the study run from?
Intensive care unit at the University of Montpellier Saint Eloi Hospital (France)

When is the study starting and how long is it expected to run for?
June 2009 to April 2011

Who is funding the study?
Fisher & Paykel Healthcare (France)

Who is the main contact?
Dr Gerald Chanques
g-chanques@chu-montpellier.fr

Contact information

Type(s)
Scientific

Contact name
Dr Gerald Chanques

Contact details
Departement d'Anesthésie-Réanimation (DAR)
Hôpital Saint Eloi
Centre Hospitalier Universitaire de Montpellier
80, avenue Augustin Fliche
Montpellier
France
34295
+33 (0)467 337 272
g-chanques@chu-montpellier.fr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V2 Apr 6th 2009

Study information

Scientific Title
Comparison of three high flow oxygen therapy delivery devices: a clinical physiological cross-over study

Study objectives
Our hypothesis was that three commonly used oxygen therapy devices (1-Optiflow™; 2-Boussignac™, and 3-standard facemask with a reservoir bag) could provide different inspired fractions of oxygen and airway pressure measured in the trachea, as well as respiratory comfort for the same oxygen flow.

To evaluate this hypothesis, a prospective physiological cross-over study was performed in ICU patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Institutional Review Board of the Saint-Eloi Teaching Hospital (Comité de Protection des Personnes Sud Méditerranée IV, Montpellier, France)
2. National Agency for Health Safety regarding Healthcare Materials (Agence Française de Sécurité Sanitaire des Produits-de-Santé), ref: ID-RCB-2009-A00190-57

Study design
Cross-over physiological study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Respiratory failure requiring critical care

Interventions
1. Optiflow™
2. Boussignac™
3. Standard facemask with a reservoir bag

Airway-pressures and Fraction of inspired oxygen (FiO2) were measured by a tracheal catheter inserted through the hole of the tracheotomy tube after removal. Comfort was also evaluated by self-reporting.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Mean airway pressure measured in the trachea

Secondary outcome measures

1. FiO2
2. Noise intensity
3. Respiratory and auditory discomfort

Overall study start date
25/06/2009

Completion date
14/04/2011

Eligibility

Key inclusion criteria
1. Consecutive patients ≥ 18 years old hospitalized in a medical-surgical ICU
2. Planned removal of a tracheotomy tube previously placed in the ICU for weaning from mechanical ventilation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
n=10

Key exclusion criteria
1. Pregnancy
2. Adult under tutelage
3. Contraindications for non-invasive ventilation, as defined by the last French consensus conference

Date of first enrolment
25/06/2009

Date of final enrolment
14/04/2011

Locations

Countries of recruitment
France

Study participating centre
Saint Eloi Hospital (Hôpital Saint Eloi)
Montpellier
France
34295

Sponsor information

Organisation
Saint Eloi Hospital (Hôpital Saint Eloi) (France)

Sponsor details
c/o Samir Jaber
Association for Research and Education in Transplantation, Anesthesiology and Critical Care (ARFTAR)
DAR B
80, avenue Augustin Fliche
Montpellier
France
34295

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04pwyfk22

Funder(s)

Funder type
Industry

Funder Name
Fisher & Paykel Healthcare (France)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2013		Yes	No